

REMARKS

This communication is responsive to the Office Action mailed December 17, 2002 (Paper No. 14), in connection with the above-identified patent application. Reconsideration of the application in view of the following remarks is respectfully requested. Claims 2-15 are pending.

A. Rejection Under the Judicially Created Doctrine of Obviousness-type Double Patenting

The rejection of claims 2-15 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-30 of U.S. Patent No. 5,834,223, is acknowledged. While Applicants respectfully traverse this rejection, it is believed that this issue is addressed by the terminal disclaimer which accompanies this response. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Rejection Under 35 U.S.C. § 102(a)

The rejection of claims 2-15 under 35 U.S.C. § 102(a) as allegedly anticipated by Sun, et. al. (*Blood*, 83, 3120, 1994), is respectfully traversed. Applicants' invention, as defined for example, by claim 2, distinguishes over Sun by requiring an *in vitro* method for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, wherein the subject is presently on an oral anticoagulant regimen. The method includes contacting a test sample comprising a coagulation factor V or Va-containing specimen from the subject with a procoagulant reagent, factor V-deficient plasma to provide coagulation factors other than factors V or Va, calcium present in a concentration from about 5 mM to 15 mM, and APC present at from about 100 ng/ml to 10 µg/ml in a test reaction.

my to 10 µg

Applicants note that in the Office Action, the Examiner asserts that Sun allegedly discloses the concentrations of calcium and APC recited in the present claims, and cites Sun, page 3120, col. 2, to support this assertion. However, Applicants submit that Sun has already been considered in parent Application No. 09/189,343 (issued U.S. Patent No. 6,083,757), which includes claims reciting a calcium range of 0.5 mM to 50 mM and an APC range of 10 ng/mL to 50 µg/mL. The calcium and APC ranges set forth in the present claims are narrower than the ranges set forth in the '757 patent. Thus, since the Patent Office has acknowledged that Sun does not anticipate the wider ranges for calcium and APC set forth in the '757 patent, it is respectfully submitted that Sun cannot anticipate present claims 2-15, which recite narrower ranges for calcium and APC. Accordingly, if the rejection is maintained, Applicants respectfully request that the basis for the rejection be clarified in a subsequent Office Action.

In summary, Sun does not disclose or suggest the specific concentration ranges for calcium and APC in a test sample as recited in claim 2. Thus, it is submitted that Sun does not describe each and every element of the claimed invention. Accordingly, reconsideration and withdrawal of the rejection of claims 2-15 under 35 U.S.C. 102(a) are respectfully requested.

Application No.: 09/606,779
Applicant: Griffin, et. al.
Filed: June 28, 2000
Page 4

PATENT
Attorney Docket No.: SCRIP1180-3

CONCLUSION

In view of the above remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: April 17, 2003



Lisa A. Haile, J.D., Ph.D.
Registration No. 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

USPTO Customer Number 28213
GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133